REMARKS

In response to the Office Action mailed June 5, 2007, reconsideration of the application is respectfully requested in view of the pending claims and the following remarks.

I. The Status of the Claims

Claims 1, 53-55, and 57-71 are pending in this application. Claims 2-52 and 56 are cancelled.

Applicants have amended claims 1, 57, 65, and 67. In particular, claims 1 and 67 have been amended as follows: (1) the term "non-absorbing" has been incorporated before the phrase "capillary matrix" (first occurrence); and (2) the blocking strip, as amended beginning at lines 11 and 6 of each of the claims, respectively, is "in planar flow communication with" the capillary matrix and lateral flow chromatography strip and, in addition, is impregnated with at least one blocking agent, "which reduces non-specific binding on the lateral flow chromatography strip."

The term "chromatographic" has been changed to "chromatography" in claims 1, 65, and 67.

With respect to claim 57, the phrase "wherein the analyte is" has been replaced with the phrase "wherein at least one analyte to be detected or quantified by at least one reagent on the lateral chromatography strip."

Support for all of the amendments is supported by the entire specification, particularly at p. 19, ll. 29-31, p. 20, ll. 2-7, and p. 22, ll. 14-16, as well as Figures 1-3. The above amendments do not introduce new matter. Accordingly, Applicants respectfully request the Examiner to enter these amendments.

Applicants respectfully submit that the rejections based on indefiniteness, obviousness and non-statutory obviousness-type double patenting are overcome in view of the amendments and arguments presented herewith.

II. Claim Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has maintained her rejection of claims 57-59 under 35 U.S.C. § 112, second paragraph, as allegedly being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular, the Examiner stated that claims 57-59 are indefinite on the ground that the "analytes cannot be part of the device of claim 56 since these analytes are collected at the time of the assay" and that "these analytes are not recited as positive limitation of the device...." Applicants respectfully traverse the rejection.

At the outset, claim 56 is a canceled claim and claims 57-59, as previously amended, depend on claim 1 and not on claim 56, as asserted by the Examiner. However, to advance prosecution, Applicants have amended claim 57 by substituting the phrase "wherein the analyte is" with the phrase "wherein at least one analyte to be detected or quantified by at least one reagent on the lateral chromatography strip is."

In light of the amendments and above remarks, Applicants respectfully submit that claims 57-59 are no longer indefinite. Reconsideration and withdrawal of the §112, ¶2 rejection of these claims are, therefore, earnestly requested.

III. Rejections Under 35 U.S.C. § 103(a)

A. Rejection of claims 1 and 53-71 over May, in view of Schlipfenbacher

Claims 1 and 53-71 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U. S. Patent No. 5,622,871 to May *et al.* (hereinafter "May"), in view of U. S. Patent No. 5,160,486 to Schlipfenbacher *et al.* (hereinafter "Schlipfenbacher"). In particular, the Examiner asserted that May "differs from the instant claimed invention in failing to teach a blocking strip and conjugate strip between the collection strip and assay strip." To cure this deficiency, the Examiner cites Schlipfenbacher, which, according to the Examiner, discloses "a blocking strip containing a buffer and a conjugate strip between the collection strip and assay strip." Thus, it would have been obvious to one of ordinary skill in the art to provide Schlipfenbacher's teachings because "Schlipfenbacher expressly teaches providing the strips as an alternative to merely having corresponding separate zones on a single strip."

Applicants respectfully traverse this rejection since May and Schlipfenbacher, either individually or in combination, fail to describe the features set forth in amended independent claims 1 and 67, as well as the rejected claims depending therefrom.

Amended independent claim 1 is directed to an apparatus for collection and lateral flow chromatography of an oral fluid that comprises the following features, namely, a housing having a cavity (*see* specification at p. 5, l. 13-18 and pp. 21-22); a non-absorbing capillary matrix extending from within the housing and protruding out from the housing for receiving oral fluid (*see* specification at p. 3, ll. 17-31; p. 5, ll. 20-26; p. 13, ll. 10-11; p. 21, ll. 16-18; and p. 22, ll. 13-16); a lateral flow chromatography strip within the housing, wherein the lateral flow chromatography strip contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid and is in planar flow communication with the capillary matrix and wherein the capillary matrix is composed of a material different from the material comprising the lateral flow chromatography strip (*see* specification at p. 4, ll. 6-8; p. 17, l. 8-p.19, l. 21; and pp. 21-22); and a blocking strip within the housing, coupled between and in planar flow communication with the capillary matrix and the lateral flow chromatography strip, wherein the blocking strip ~~is~~ impregnated at least one blocking agent which reduces non-specific binding on the lateral flow chromatography strip (*see* specification at p. 5, ll. 5-9; p. 19, l. 25-p. 20, l. 14; p 21; and p. 22, ll. 14-16).

Amended independent claim 67, besides reciting all the elements of amended claim 1, also includes (1) a conjugate pad within the housing that contains lateral flow chromatography reagents and is coupled between the blocking pad and the lateral flow chromatography strip (*see* specification at p. 5, ll. 10-12, p. 20, ll. 16-27 and p. 21), and (2) at least one inspection site from an exterior of the housing to the lateral flow chromatography strip to help in visualization of the test outcome (*see* specification at p. 5, ll. 13-18 and pp. 21-22).

As illustrated in the specification at pp. 21-22 and Figures 1 and 3 (see below), the claimed apparatus comprises a lateral flow chromatography strip (C) that is disposed lengthwise within the housing (H). One end of the chromatography strip (C) contacts directly, or by way of blocking pad (B) with a portion of capillary matrix (W). The capillary matrix (W) projects out of the housing (H) where it presents a face (3) that acts as an absorbent surface for uptake of oral fluid. The oral fluid migrates through the matrix (W) and

through the blocking pad (B), where it is finally delivered to a receiving area (R) on the lateral flow chromatography strip (C). The oral fluid then migrates along the lateral flow chromatography strip (C) where it interacts with various reagents that are deposited within the chromatography strip (C) and/or within optional conjugate strip (G), which, when present, contacts the chromatography strip (C).

Also illustrated in Figure 3, the capillary matrix protrudes out from the housing to provide a planar surface for insertion into the oral cavity where the capillary matrix face (3) can be contacted with the oral mucosa. *See* specification at p. 22, ll. 14-16.

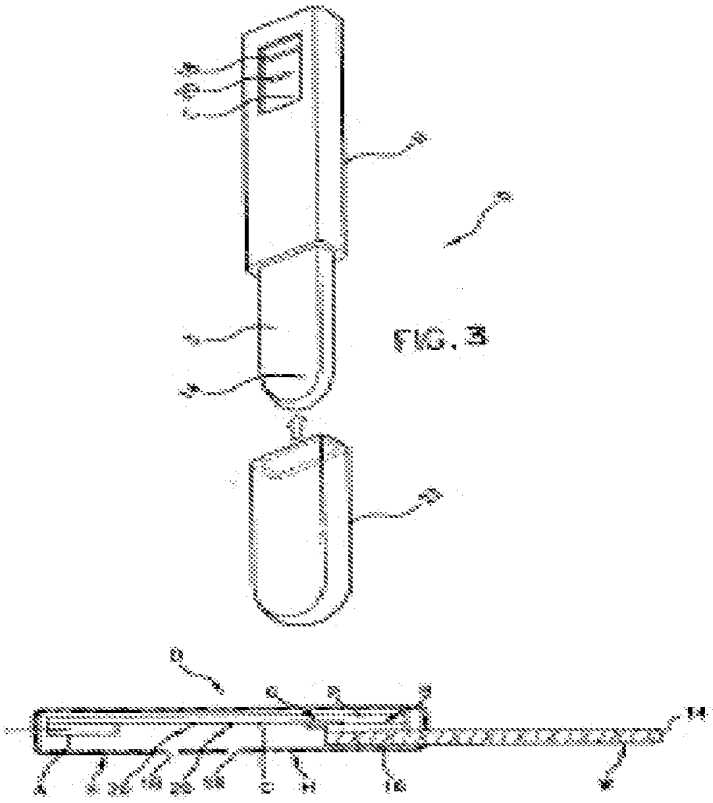

FIG. 3

FIG. 1

Based on the above, the claimed invention is distinct from May and Schlipfenbacher. This is because May and Schlipfenbacher, either individually or in combination, fail to disclose or suggest an apparatus for collection and lateral flow chromatography of oral fluid

that includes a blocking strip, which is impregnated with at least one blocking reagent that reduces non-specific binding on the lateral chromatography strip.

The Examiner points to column 16, line 67-column 17, line 40 of May as teaching a "chromatographic test strip contained within the housing having at least one blocking agent or buffer." Final Off. Act., p. 13. May, in fact, does not teach such a chromatographic strip. This portion of May describes the preparation of the Anti-hCG-Dye Sol, a process in which protein may be coupled to a dye sol by passive absorption. May uses a blocking agent to block excessive binding sites on the sol, after the protein is added. The antibody-sol conjugate is separated from the solution by centrifugation and freeze dried for use. May does not teach or suggest applying the blocking agent to any portion of the lateral flow strip. May is not concerned with non-specific binding to the lateral flow chromatography strip, as in the claimed invention. To the contrary, May is concerned with non-specific binding to the antibody-sol conjugate. Nothing in May or Schlipfenbacher would lead one of ordinary skill to employ a blocking agent on a blocking pad to reduce non-specific binding to the lateral flow chromatography strip as in the claimed invention.

In addition, the material that comprises the sample application zone (start zone, equivalent to the capillary matrix of the claimed apparatus) of Schlipfenbacher is different from that of the claimed invention. The sample application zone, according to Schipfenbacher, is made up of at least 50% of absorbent fleece materials, such as polyamides and polyesters as well as mixtures thereof, in combination with the fibers of polyvinylalcohol. Contrary to Schlipfenbacher, the material that comprise the capillary matrix of the claimed apparatus is a non-absorbing material.

Based on these foregoing reasons, one of ordinary skilled in the art would not combine the device of May or test carrier of Schlipfenbacher if the materials employed by both references vary from each other. In addition, neither references teaches the impregnation of at least one blocking agent on the blocking strip to arrive at Applicants' claimed invention. Applicants respectfully submit that May and Schlipfenbacher, taken alone or in combination, fail to render claims 1 and 67, as well as the claims dependent therefrom, obvious.

Based on the remarks and amendments presented above, Applicants respectfully submit that the Examiner has failed to establish the *prima facie* obviousness of claims 1 and

53-71. Reconsideration and withdrawal of the §103(a) rejection of these claims is, therefore, earnestly requested.

B. Rejection of claims 1, 53-55, 57-58, 60-65 and 67-71 over Moorman, in view of Ching

Claims 1, 53-55, 57-58, 60-65 and 67-71 under 35 U.S.C. §103(a) as being unpatentable over U. S. Patent No. 5,820,826 to Moorman (hereinafter "Moorman"), in view of U. S. Patent No. 5,120,643 to Ching *et al.* (hereinafter "Ching").

In rejecting these claims, the Examiner considered the blocking strip of the presently claimed invention as being equivalent to Moorman's blocking strip. This reasoning is based on Moorman's disclosure of the use of two double-sided tapes "to block the flow of the fluid, *i.e.*, a blocking strip, and the one way flow regulating means, in addition to its functions as a blocking means, may also contain reagents such as buffers (column 11, lines 12-21 and lines 49-51)." The Examiner asserted that the "instant claims do not specifically define the blocking strip" and "requires only that it contains at least one blocking agent and is disposed between a sample collection matrix and a chromatography strip" and, therefore, "such a strip is clearly taught by Moorman."

Besides the blocking strip, the Examiner also considered Moorman's sponge (identified as zone 26 in Figure 2) is equivalent to the claimed capillary matrix that "functions as a sample application area," which "must have an exposed surface, otherwise fluid cannot be applied to it."

Applicants respectfully traverse this rejection.

Applicants respectfully submit that the Examiner, upon the examination of the pending claims, must give these claims the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969). When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As set forth in p. 19, l. 1 – p. 20, l. 7, of the specification, the blocking strip is "a strip between the porous matrix and the lateral flow chromatography strip" that (1) "can be impregnated with buffers to adjust the pH of the oral fluid for compatibility with the lateral flow

chromatography assay" and (2) "can include one or more blocking reagents that reduce non-specific binding of the analyte and/or reagents of the assay device thereby reduce the occurrence of false positives." As set forth in claims 1 and 67 and described in the specification at p. 19, ll. 29-31, the blocking strip is impregnated with at least one blocking agents (*see* p. 20, ll.1-2) that reduce non-specific binding on the lateral flow chromatography strip. The blocking reagents can be bovine serum albumin, deoxycholate and n-lauroyl-sarcosine, as well as the compositions of two blocking solutions (*see* p. 20, ll. 2-7). Thus, as disclosed, the specification is "the primary basis for construing the claims" (citing *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)). Accordingly, contrary to the Examiner's contentions, Moorman's blocking strip, *i.e.*, flow regulating means "29," whose function is to "block the liquid from going forward, forcing it to move down and into the substrate pad and, therefore, establishing a predefined channel for directional fluid flow through the structure pad (component 27, *see* Moorman at col. 10, ll. 59- 67), cannot be equivalent with the claimed blocking strip of the present invention. Furthermore, Moorman's examples of blocking material include the double stick tapes and hardened hot melted adhesives, which functions differently from that of the claimed invention.

Moorman's absorptive means, structure 26, comprising absorptive material for application of a fluid thereto (*see* Moorman at col. 10, ll. 22-23) does not correspond to the claimed capillary matrix of the present invention. As set forth in Moorman, absorptive means 26 is positioned above the substrate pad (structure 27) to "allow the moistening agent" or "run buffer" to be applied into it. By using the double stick tapes (28 and 28'), the fluid can only go into the front end of the substrate pad and, at the same time, forcing the fluid to move downward into the substrate pad (lateral flow chromatography strip). (*see* Moorman at col. 10, l. 46-54). The materials that constitute Moorman's structures 26 and 27 are limited only by the requirement that they be absorbent and inert relative to the reagents which contact them. (*See* Moorman at col. 11, ll. 22-24). An example of such absorbent material is a sponge. Contrary to Moorman's absorptive means, the claimed capillary matrix is a non-absorbing material and is not positioned above the lateral flow chromatography strip. Instead, it lies next to the lateral flow chromatography strip and is in direct communication to the strip. As described in the specification, the "components were assembled such that the lateral flow chromatography strip was disposed lengthwise within the straw and appressed at one end to and end of the capillary matrix." The flow of the oral fluid would be forward and

not downward as Moorman. More importantly, the materials that comprise the claimed capillary matrix and lateral flow chromatography strip, as recited in amended independent claims 1 and 67, are different from each other. Also of importance is that the capillary matrix of the claimed invention is a hydrophilic porous plastic matrix that is "essentially non-absorbing" but adsorbs (instead of absorbing liquid as taught and suggested by Moorman) liquid via capillary action and delivers the oral fluid the lateral flow chromatography strip. (*See* p. 5, ¶ 0055, ll. 1-3 and p. 4, ¶0044, ll. 6-9). Moreover, claimed capillary matrix, as disclosed in the specification, at p. 6, ¶0063, ll. 4-7, "acts more as a conduit than as an absorbent; material is readily discharged from the wick."

In addition to the above-mentioned differences, Moorman fails to disclose or suggest the claimed apparatus for collection and lateral flow chromatography of oral fluids wherein the lateral flow chromatography strip contains at least one reagent that is used to detect or quantify at least one analyte in the oral fluid.

According to the Examiner, Moorman fails to disclose the use of blocking agents. However, the deficiency, as pointed out by the Examiner, can be found in the Ching reference. Ching, as asserted by the Examiner, discloses "devices using labeled specific binding materials including colloidal particle and enzyme labeled materials which are dried onto a chromatographic medium in the presence of a meta-soluble protein…" and "impregnating solid substrate materials with meta-soluble proteins such as bovine serum albumin and detergents, *e.g.*, sodium deoxycholate, *etc*."

In view of Ching, the Examiner concluded that it would have been obvious to one of ordinary skill in the art to "add the meta-soluble proteins as taught by Ching to the blocking means or substrate pad of Moorman because additional features may be incorporated into the apparatus including antibodies, signal inhibitors, buffers and so forth." In addition, Ching, according to the Examiner, "teaches that improved assay results is achieved using the meta-soluble agents." The Examiner further concluded that "a skilled artisan would have had a reasonable expectation of success" when adding Ching's meta-soluble agents to Moorman's device because Moorman has indicated that "the addition of agents such as buffers and the like are well known in the art" and "the choice of appropriate agents is chosen on the basis of the aim of the assay and the type of analytes."

Applicants respectfully submit that Ching, like Moorman, fails to disclose or suggest the claimed apparatus for collection and lateral flow chromatography of oral fluids that comprises the features of claims 1, 53-55, 57-58, 60-65 and 67-71. In particular, Ching is completely silent with respect to the claimed lateral flow chromatography strip and blocking strip that contains blocking agents, as recited in the above-mentioned claims. In addition, Ching, like Moorman, also fails to disclose the impregnation of a chelating agent on the blocking pad.

Ching cannot remedy the deficiencies of Moorman, as discussed above. One of ordinary skill in the art would not be motivated to combine both Moorman and Ching or have any reasonable expectation of success to arrive at the claimed invention.

Based on the above-mentioned remarks and amendments, Applicants respectfully submit that Moorman and Ching, either individually or in combination does not render obvious claims 1, 53-55, 57-58, 60-65 and 67-71. Applicants respectfully request the reconsideration and withdrawal of this rejection and the allowance of these claims.

C. Rejection of claim 59 over Moorman, in view of Ziegelmaier

The Examiner rejected claim 59 under 35 U.S.C. §103(a) as being unpatentable over Moorman, in view of Ching, as applied to claims 1 and 55-57 (56 is canceled), and further in view of U. S. Patent No. 6,632,628, to Ziegelmaier *et al.* (hereinafter "Ziegelmaier"). According to the Examiner, Moorman, who "differs from the instant claims in failing to teach the detection of hepatitis," "does teach that the analyte and the analyte specific receptors are chosen on the basis of the aim of the assay and discloses typical tests including assays for etiological agents for infectious diseases." However, Moorman's deficiency, as asserted by the Examiner, can be cured by Ziegelmaier, whose claimed invention is directed to "assays for etiological agents for infectious diseases such as HIV, rubella, hepatitis A and B, *etc.*" Applicants respectfully traverse this rejection.

Ziegelmaier does teach a one-step immunoassay for the determination of antigen-specific antibodies directed against the above-mentioned infectious diseases. Like Moorman and Ching, Ziegelmaier also fails to disclose or suggest the claimed apparatus for detecting at least one analyte that is an antibody to hepatitis. More particularly, Ziegelmaier fails to cure the deficiency of Moorman and Ching. As remarked above, Moorman is not a patent-defeating reference with respect to the subject matter of claims 1, 55, and 57-59.

Accordingly, Moorman, Ching and Ziegelmaier neither disclose nor suggest elements of claims 1, 55, and 57-59. Applicants respectfully submit that Moorman, Ching and Ziegelmaier do not render claim 59 obvious.

D. Rejection of claims 1, 53, 55, 57-58, 60-61 and 63-71 over Kremer, in view of Sangha and de Zoeten,

Claims 1, 53, 55, 57-58, 60-61 and 63-71 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U. S. Patent No. 4,635,488 to Kremer *et al.* (hereinafter "Kremer"), in view of U. S. Patent No. 5,334,502 to Sangha *et al.* (hereinafter "Sangha") and U. S. Patent No. 5,611,995 to de Zoeten (hereinafter "de Zoeten").

The Examiner stated that "Kremer differs from the instant claims in failing to teach that the blocking strip comprises blocking agents and detergents or buffers." Such deficiency by Kremer, however, can be cured by Sangha and De Zoeten, both of which, according to the Examiner, discloses (1) a test card for detecting analytes in a saliva sample comprising tretramethylbenzidine (TMB) dissolved in dimethyl formamide (DMF) or dimethyl sulfoxide (DMSO) and EDTA impregnated thereon and dried" and (2) "conventional blocking agents such as polyvinylalcohol, or human and bovine serum albumin," respectively.

Based on the combined teachings of Kremer, Sangha, and De Zoeten, the Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to place reagents such as buffers and detergent taught by Sangha and de Zoeten in the device of Kremer because Sangha and de Zoeten teach that such reagents are well known in the art as providing the advantage of improving assay results by maintaining appropriate pH of the sample and dissolving interference material prior to contacting the sample with the test reagents. A skilled artisan would have had a reasonable expectation of success in placing these reagents on the strip of Kremer because Sangha teaches a blocking strip made of the same material as that of Kremer which can incorporate reagents such as dyes, and de Zoeten teaches adding buffering compounds to a sample collector (also made of the same material) to adjust pH of the test liquid and therefore, absent unexpected results, these limitations are seen to be obvious in view of the teachings of Kremer as modified by Sangha and de Zoeten." Applicants respectfully traverse this rejection.

Kremer discloses a sampling device that includes a hollow tube having "at least one open end, and a collecting nib secured in that open end of the tube and having an inner

extremity facing the interior of the tube and an outer tip projecting beyond the last mentioned end of the tube for contact with a fluid (*e.g.*, sweat, tears or saliva) to be collected" (col. 2, ll. 49-55). The nib comprises a solid, nonfibrous, porous, water-wettable body having porosity sufficient for absorption of the fluid to be collected (col. 2, ll. 55-57). Based upon Kremer's disclosure, a sampling device having a hollow tube with one cap and one open end is used for collecting body sample fluids. On the other hand, a sampling device having a further cap (structure 16) for closing the second open end (structure 18), as disclosed by Kremer, is used not only for sample collect but also for sample analysis since the hollow tube is in direct contact with an analysis element (structure 44 (strip) or structure 46 (column)). The analysis element incorporates an agent which undergoes an observable change upon contact with a substance to be detected (col. 6, ll. 44-50 and can be removed from the hollow tube after absorbing the sample, for subsequent analysis (col. 3, ll. 56-58).

In addition, a "nib" as defined in the Webster's College Dictionary, 2000, at p. 893, col. 1, refers to (a) "a penpoint or one of the two segments of a split penpoint;" or (b) "any pointed end." As illustrated in Figures 1 and 6 of Kremer, the collecting nib (12), as well as its exposed tip (28) does not correspond to and is distinct from the claimed capillary matrix (W) or (3), as illustrated in Figures 1 and 3, respectively, of the specification (*see supra).* The claimed capillary matrix**,** as recited in amended claims 1 and 67, "projects out of " or "protrudes from" "the housing" to "provide a planar surface" for receiving oral fluid (*see* specification at p. 21, ll. 16-18 and p. 22, ll. 14-16).

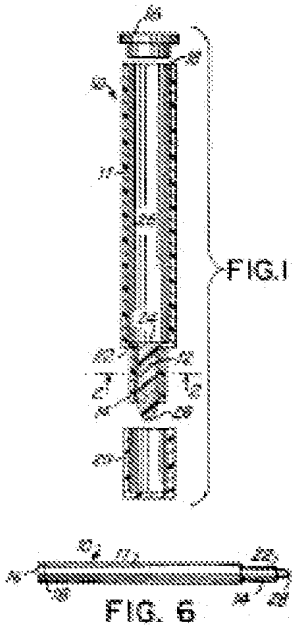

FIG. 6

In addition, the claimed lateral flow chromatography strip is enclosed inside the housing and is in direct contact with the capillary matrix. It also contains at least one reagent for use in detecting or quantifying at least one analyte in the oral fluid, such feature is absent in Kremer. Also absent is the presence of the blocking strip impregnated with at least one blocking agent (the latter was acknowledged by the Examiner in the Office Action). The claimed blocking strip is not equivalent to the hydrophobic body of Kremer. The function of the claimed blocking strip, as set forth in independent claims 1 and 67, to reduce non-specific binding of the analyte or reagents on the lateral flow chromatography strip. In contrast, hydrophobic body of Kremer is for prevention of premature transfer of samples to the analysis element (see Office Action, p. 18, 2nd full paragraph, ll. 4-6). With respect to claim 67, Kremer fails to disclose or suggest a conjugate strip that is coupled between the blocking strip and lateral flow chromatography strip.

Sangha discloses a method and device for collecting and identifying saliva for analysis and sample verification. The method comprises obtaining a saliva sample from a subject using a sample probe and application of the sample to an absorbent sheet or layer. The sample probe is composed of support stick having swab for sample collection (col.5, ll. 44-48). An example of the sample probe, as provided by Sangha and also cited by the

Examiner in the Office Action (p. 9), is presented in Figure 8. As shown, a capillary tube 78 surrounds absorbent 80 and on top of absorbent 80 is one-way barrier 82 containing indicator component 84. As saliva migrates or is wicked along absorbent 80, it approaches barrier 82, which is situated atop absorbent 80. The saliva will pass through one way barrier 82 to interact with indicator component 84. The indicator component can be either a vegetable dye or a colorless substrate which act as a chromogen in the presence of saliva. The Examiner asserted that Sangha also discloses "a test card for detecting the saliva sample (col. 15, ll. 13-27).

Similar to Kremer, Sangha fails to disclose the claimed apparatus as set forth in claims 1 and 67 of the present invention. Sangha is silent with respect to the claimed lateral chromatography strip and blocking strip, as well as the conjugate strip with respect to claim 67. There is no suggestion or motivation to combine both of Kremer's and Sangha's teachings for one of ordinary skill in the art to arrive at the claimed invention.

De Zoeten discloses an apparatus having a housing and holding device (can be separable from the housing) for holding a test strip comprising a sample collector which can readily absorb test liquid, but also easily release the liquid under capillary transfer. According to De Zoeten, the transfer of the liquid sample from the sample collector to the test strip can be achieved by simply pressing or indirectly by capillary means using a connector (col. 4, ll. 34-49). This is contrary to the claimed invention where transport of the oral fluid to the lateral chromatography strip is accomplished without any manipulation or compression of the matrix material itself (see specification at p. 12, l. 1 - p. 13, l. 2). De Zoeten does teach the use of a nitrocellulose test strip that is directly coupled with antibodies without a previous chemical treatment on the test strip. After coupling, however, the remaining binding sites on the same test strip should be blocked by treating the test strip with hydrophilic synthetic polymers such as polyvinylalcohol or hydrophilic biopolymers such as bovine serum albumin or ovalbumin (col. 7, ll. 5-11). This is distinctly different from the claimed apparatus of the present invention where a separate blocking strip or pad is provided and is coupled between the capillary matrix and lateral flow chromatography strip. Accordingly, De Zoeten is not a patent-defeating reference to the presently claimed invention.

None of these references, Kremer, Sangha and De Zoeten, either alone or in combination, suggests an apparatus for collection and lateral flow chromatography of oral

fluid, in particular, the claimed features of the lateral flow chromatographic strip, a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip impregnated with at least one blocking agent. Therefore, Applicants respectfully submit that Kremer, Sangha and De Zoeten, either individually or in combination do not render obvious 1, 53, 55, 57-58, 60-61 and 63-71. Moreover, Applicants respectfully submit that the Office Action has failed to establish a motivation to combine the primary reference and secondary references as suggested by the Examiner. There is no reasonable expectation of success either.

Based on the above reasons, Applicants respectfully submit that the Examiner has failed to establish the *prima facie* obviousness of claims 1, 53, 55, 57-58, 60-61 and 63-71. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §103(a) rejection of these claims.

E. Rejection of claim 62 over Kremer or Moorman, in view of Sangha and de Zoeten, as applied to claims 1, 53, 55-58, 60-61 and 63-69, and further in view of Porex Technologies Catalog, 1995

At page 11 of the Office Action, the Examiner rejected claim 62 under 35 U.S.C. 103(a) as being unpatentable over Kremer or Moorman, in view of Sangha and de Zoeten, as applied to claims 1, 53, 55, 57-58, 60-61 and 63-71, and further in view of Porex Technologies Catalog, 1995. The Examiner acknowledged that Kremer, Moorman, Sangha and de Zoeten fail to "teach a capillary matrix having an average pore size from about 40 to 250μm. The deficiency found in all these references, according to the Examiner, however, is cured by Porex's disclosure of porous plastics available in molded shapes, sheets, rods and tubes having an average pore size from 7 to greater than 250 micrometers. The Examiner further asserted that "Porex engineers can also develop custom designs for specific use which will take into consideration strength, sample flow, durability and shape." Based on these assertions, the Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to choose a porous nib with the desired pore size such as taught by Porex for use in the device of Kremer or Moorman, as modified by Sangha and de Zoeten because these parameters are dependent on the nature of the assay, *i.e.*, samples to be tested and reagents involved." The Examiner further asserted that a skilled artisan would have had a reasonable expectation of success in choosing from any of the disclosed nibs or to have nibs specification made to fit their needs. According to the

Examiner, "the selection of a specific material is generally dependent on the assay and the characteristics of the sample, therefore, absent unexpected or improved results, selection of nibs with specific pore sizes so as to optimize the performance of a device is seen to be obvious in view of the teachings of Kremer or Moorman and Porex Technologies." Applicants respectfully traverse this rejection.

As remarked earlier and in light of the amendments presented hereinabove, Applicants respectfully submit that Kremer, Moorman, Sangha, or de Zoeten, either alone or in combination, fails to teach the subject matter of claim 1 and its dependent claim 62. In addition, the Porex Technologies Catalog, as cited by the Examiner, also fails to cure the combined deficiencies of these references. Applicants respectfully submit that Kremer, Moorman, Sangha, de Zoeten and the Porex Technologies Catalog all fail to render obvious claim 1 and its dependent claim 62. Moreover, Applicants respectfully submit that the Examiner has failed to provide any reasonable expectation of success to arrive at the claimed invention. In addition, the Examiner also fails to establish a motivation to combine Kremer, Moorman, Sangha, de Zoeten and the Porex Technologies Catalog.

Based on the above reasons, Applicants respectfully submit that the Examiner has failed to establish the *prima facie* obviousness of claims 1 and 53-69. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §103(a) rejection of these claims.

III. Non-Statutory Obviousness-Type Double Patenting Rejection

On page 12 of the Office Action, the Examiner provisionally rejected claims 1, 53, 55-61 and 63-71 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 67-80 and 51-53 of U.S. Patent No. 7,192,555 B2 (Application No. 09/973,956).

As previously indicated, Applicants will file a suitable terminal disclaimer once the claims are indicated to be allowable.

Finally, Applicants respectfully submit that all of the §112, ¶2, §103(a) and non-statutory obviousness-type double patenting rejections of the pending claims have been overcome. Reconsideration and withdrawal of these rejections are earnestly requested.

CONCLUSION

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. The Commissioner is hereby authorized to charge any payment deficiency to Deposit Account No. 19-2380 referring to Docket No. 030793-036100.

Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicants' representative designated below.

Respectfully submitted,

Date: October 31, 2007

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